12-22-05

DAC/1fw/B

CASE 4-30972A

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10	
EV 722485605 US Express Mail Label Number	December 21, 2005 Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF
BRAIN ET AL.
INTERNATIONAL APPLICATION NO: PCT/EP00/05059
FILED: 2 JUNE 2000
U.S. APPLICATION NO: 10/009,009
35 USC §371 DATE: 20 DECEMBER 2001
FOR: BRADYKININ RECEPTOR ANTAGONISTS

Art Unit: 1624
Examiner: T. McKenzie

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 CFR §1.705(d) FOR PATENT TERM ADJUSTMENT

Sir:

Patentees hereby respectfully petition under 37 CFR §1.705(d) for a 330 day patent term adjustment for U.S. Patent No. 6,958,331, which issued on October 25, 2005. This patent is not subject to a terminal disclaimer. The patent term adjustment is requested due to following relevant dates and circumstances:

1. On March 4, 2004, an Office Action was mailed to Patentee, indicating that claims 1, 3, 4, 12-14, 16 and 17 are allowed and that claim 18 is rejected.
2. On March 3, 2004, prior to the mailing of the Office Action in #1, Examiner initiated a telephonic interview with the Patentee. It is noted on the Examiner-Initiated Interview Summary that "Applicants agreed to limit claim 18 to the treatment of pain."
3. On March 16, 2004, Patentees received a Notice of Allowance for Application No. 0/009,009, indicating that the issue fee was due on June 16, 2004, a Notice of Allowability indicating that claims 1, 3, 4, 12-14 and 16-18 were allowed. The Notice of Allowability indicated that the communication was responsive to telephone interview of 3/3/04.
4. On June 16, 2004, prior to the deadline for filing the Issue Fee, Patentees paid the Issue fee.

12/23/2005 HDEMESS2 00000062 190134 10009009
01 FC:1455 200.00 DA

5. On July 26, 2004, Patentee filed a Communication in response to telephonic request from the U.S. Patent and Trademark Office on that day to supply legible copies of page 10 and 11 of the patent application. This Communication was not a response to any outstanding Office Action.
6. On October 5, 2005, Patentees received an Issue Notification indicating an issue date of October 25, 2005, and a Patent Term Adjustment of 210 days.
7. On October 25, 2005, U.S. patent No. 6,958,331 granted.

In view of the above, Patentees request a Patent Term Adjustment of 330 days as opposed to the 210 days indicated on the Issue Notification. Patentees would have been entitled to 389 days pursuant to 37 CFR §1.703(a), that being the total number of days based on:

1. 15 days – the number of days beyond 14 months from the filing date until the first Office Action time after 14 months. (Application was filed on December 20, 2001 and the first Office Action was mailed on March 7, 2003.); and
2. 374 days – the number of days beyond 4 months from the payment of issue fee until patent grant. (Issue fee was paid on June 16, 2004 and US 6,958,331 granted October 25, 2005.).

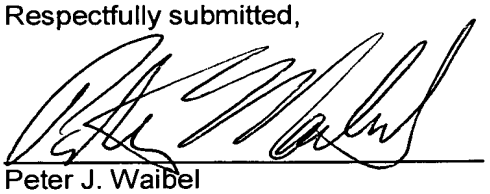
This Patent Term Adjustment of 389 days would be reduced under 37 CFR §1.704(b) by the number of days of delay due to actions by the Patentee, i.e., extensions in time to respond to Office Actions beyond the required period of reply. This reduction is believed to be limited to 59 days based on a response filed on August 5, 2003. (Office Action was mailed on March 7, 2003 and Response was filed on August 5, 2003 – 59 days beyond the three month period for reply).

Accordingly, Patentees request a Patent Term Adjustment of 330 days (389 days – 59 days).

It is believed that the PTO has improperly calculated the number of days for the reduction of the 389 days available under 37 CFR §1.703(a). Based on review of the prosecution, it appears that there is no action by Patentees that delayed prosecution for the 120 day difference between the Patent Term Adjustment noted on the Issue Notification and Patentee's calculation above. Patentees believe that they should not be penalized for more than 59 days under 37 CFR 1.704(b).

Please charge $200 to Deposit Account No. 19-0134 in the name of Novartis Corporation, this amount being the fee required by 37 CFR 1.18(e) for filing an application for patent term adjustment under §1.705. Two additional copies of this page are appended.

Respectfully submitted,



Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080

Peter J. Waibel
Attorney for Applicants
Reg. No. 43,228
(862) 778-7951

Encls.: Copy of:

- Issue Notification dated October 5, 2005
- Communication dated July 26, 2004 with replacement pages 10 and 11
- Issue Fee dated June 16, 2004
- Notice of Allowance and Fees Due dated March 16, 2004
- Determination of Patent Term Adjustment Under 35 USC 154(b) dated March 16, 2004
- Notice of Allowability dated March 16, 2004
- Examiner-Initiated Interview Summary
- Office Action dated March 4, 2004
- Office Action Summary
- Amendment dated August 5, 2003 with Postcard receipt
- Office Action dated March 7, 2003
- Office Action Summary

Date: December 21, 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,009	10/25/2005	6958331	4-30972A	1971

1095 7590 10/05/2005

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EJW

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 210 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

APPLICANT(s) (up to 18 names are included below, see PAIR WEB site http://pair.uspto.gov for additional applicants):

Christopher Thomas Brain, London, UNITED KINGDOM;
William Cantrell, San Antonio, TX;
Andrew James Culshaw, London, UNITED KINGDOM;
Edward Karol Dziadulewicz, London, UNITED KINGDOM;
Terance William Hart, London, UNITED KINGDOM;
Timothy John Ritchie, London, UNITED KINGDOM;
Liladhar Waykole, Succasunna, NJ;

ENTERED

OCT 18 2005

Linda Rothwell

CASE 4-30972A

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 540154162 US
Express Mail Label Number

July 26 2004
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
BRAIN ET AL.
APPLICATION NO: 10/009,009
FILED: DECEMBER 20, 2001
FOR: BRADYKININ RECEPTOR ANTAGONISTS

Art Unit: 1624
Examiner: T. McKenzie

Attention: Janet Higgins
U.S. Patent and Trademark Office
2231 Crystal Drive
Suite 910
Arlington, VA 22202

COMMUNICATION

Sir:

As per our discussion by telephone today to supply you with legible copies of pages 10 and 11 of this application, enclosed are replacement pages 10 and 11 for your records.

Please do not hesitate to call if you have further questions.

Respectfully submitted,

Edward J. Wilusz, Jr.
Attorney for Applicants
Reg. No. 52,370
(862) 778-7960

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080

Date: July 26, 2004

Compound	R^{3A}	m	n	R^{6A}
5.23	5-methylisoxazol-3-ylmethyl	2	0	$-CH_3$
5.24	2-methylthiazol-4-ylmethyl	2	0	$-CH_3$
5.25	$-CH_2CHC(CH_3)_2$	2	0	$-CH_3$
5.26	$-CH_2CHCHCH_3$	2	0	$-CH_3$
5.27	$-CH_2C_6H_{11}$	2	0	$-CH_3$
5.28	$-CH_2C_4H_7$	2	0	$-CH_3$
5.29	$-CH_2CCCH_3$	2	0	$-CH_3$
5.30	thiophen-3-ylmethyl	2	0	$-CH_3$
5.31	thiophen-2-ylmethyl	2	0	$-CH_3$
5.32	$-CH_2CCCH_2CH_3$	2	0	$-CH_3$
5.33	$-CH(CH_3)_2$	2	0	$-CH_3$

CHARACTERISING DATA

Compounds of the above tables are found to exhibit the following HPLC retention data [min]:

No.	[min]	No.	[min]	No.	[min]	No.	[min]
1	5.91*	1.5	7.17****	26	24.95***	5.15	6.083*
2	5.68*	1.6	5.0*****	27	5.90*	5.16	6.100*
3	6.22*	1.7	5.7*****	28	6.23*	5.17	6.067*
4	5.43**	16	24.03***	29	5.35*	5.18	5.967*
5	23.55***	17	4.6****	30	5.75*	5.19	4.767*
6	5.24**	18	20.1***	5.1	5.833*	5.20	4.667*
7	25.93***	19	22.6***	5.2	6.367*	5.21	5.567*
8	5.09**	20	22.58***	5.3	6.100*	5.22	6.02*
9	23.98***	21	27.57***	5.4	6.250*	5.23	6.138*
10	23.89***	22	22.9***	5.5	6.167*	5.24	6.087*
11	6.37*	3.1	5.03*****	5.6	6.45*	5.25	6.558*
12	23.68***	3.2	5.8*	5.7	6.200*	5.26	6.382*
13	5.10**	3.3	5.83*	5.8	5.467	5.27	6.932*
14	6.17****	3.4	3.4*****	5.9	6.167*	5.28	6.547*
15	5.28****	4.1	5.467*	5.10	5.900*	5.29	6.26*
1.1	4.95*****	4.2	5.822*	5.11	6.338*	5.30	6.453*

No.	[min]	No.	[min]	No.	[min]	No.	[min]
1.2	6.00****	23	5.57*	5.12	6.998*	5.31	5.7*****
1.3	6.4****	24	5.9*	5.13	6.983*	5.32	5.7*****
1.4	6.82****	25	23.82***	5.14	7.03*	5.33	6.510*

HPLC conditions:

*: Hypersil 3 micron C 18 BDS column. Gradient elution 10-100% MeCN in water (+0.1% TFA) over 10 min

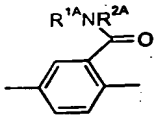
**: Kingsorb 50x4.6mm C18 column, 3micron particle size; flow rate 3ml/min; 90% water (+10mM NH_4OAc 0.3% HCOOH) 10% MeCN to 100% MeCN over 10min

***: Nucleosil 5 micron C18 column, 25cm x 4.6mm. Gradient elution 10-100% MeCN in water (+0.1% TFA) over 40 min

****: Waters Symmetry 3 micron C18 column; 5 x 0.46 cm. Gradient elution, 10% to 100% MeCN in water (+ 0.1% TFA) over 10 min

*****: Kingsorb 3 micron C18 column, 30x4.6mm, gradient elution 10 % MeCN in water (+0.1% TFA) to 100% MeCN over 10 min

Compounds of formula IIA wherein X^1, R^9 and R^{10} have the above meanings and X^2 is a divalent group of formula



wherein R^{1A} and R^{2A} independently are C_1-C_4alkyl or, together with the N-atom to which they are attached, represent a 5 to 7 membered heterocyclic ring,

may be prepared applying known techniques, e.g. in accordance with the following reaction scheme:

ART B - FEE(S) TRANSMITTAL

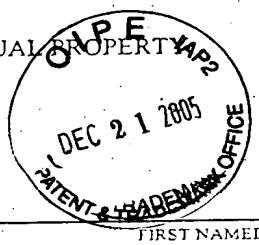
plete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (703) 746-4000

RUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where priate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as ated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for enance fee notifications.

RRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

001095 7590 03/16/2004

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080



Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

Filing by Express Mail	(Depositor's name)
See Stamp Below:	(Signature)
	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,009	12/20/2001	Christopher Thomas Brain	4-30972A	1971

E OF INVENTION: BRADYKININ RECEPTOR ANTAGONISTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1330	$0	$1330	06/16/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
MCKENZIE, THOMAS C	1624	514-227800

ange of correspondence address or indication of "Fee Address" (37 1.363).

Change of correspondence address (or Change of Correspondence ddress form PTO/SB/122) attached.

"Fee Address" indication (or "Fee Address" Indication form TO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer umber is required.**

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Joseph J. Borovian
2 E. Jay Wilusz
3

SSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

LEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has een previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: **Novartis AG**

(B) RESIDENCE: (CITY and STATE OR COUNTRY): **Basel, Switzerland**

se check the appropriate assignee category or categories (will not be printed on the patent); ☐ individual ☒ corporation or other private group entity ☐ government

he following fee(s) are enclosed:
☒ Issue Fee
☐ Publication Fee
☐ Advance Order - # of Copies 10

4b. Payment of Fee(s):
☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number 19-0134 (enclose an extra copy of this form).

ctor for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

horized Signature) Edward J. Wilusz (Date) 6/16/04

OTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone ier than the applicant; a registered attorney or agent; or the assignee or other party in erest as shown by the records of the United States Patent and Trademark Office.

is collection of information is required by 37 CFR 1.311. The information is required to tain or retain a benefit by the public which is to file (and by the USPTO to process) an plication. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is imated to take 12 minutes to complete, including gathering, preparing, and submitting the mpleted application form to the USPTO. Time will vary depending upon the individual se. Any comments on the amount of time you require to complete this form and/or ggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. tent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. ND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.

der the Paperwork Reduction Act of 1995, no persons are required to respond to a llection of information unless it displays a valid OMB control number.

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10
EL997255527US
Express Mail Label Number
June 16, 2004
Date of Deposit

TRANSMIT THIS FORM WITH FEE(S)

)L-85 (Rev. 11/03) Approved for use through 04/30/2004. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

001095 7590 03/16/2004

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERT
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
MCKENZIE, THOMAS C	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/16/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,009	12/20/2001	Christopher Thomas Brain	4-30972A	1971

TITLE OF INVENTION: BRADYKININ RECEPTOR ANTAGONISTS

JJB

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1330	$0	$1330	06/16/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 11/03) Approved for use through 04/30/2004.

DOCKETED FOR: June 16, 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,009	12/20/2001	Christopher Thomas Brain	4-30972A	1971

001095 7590 03/16/2004

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
MCKENZIE, THOMAS C	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/16/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 11/03) Approved for use through 04/30/2004.

Notice of Allowability	Application No. 10/009,009	Applicant(s) BRAIN ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included ewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS TICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative he Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

☒ This communication is responsive to *TELEPHONE INTERVIEW OF 3/3/04*.

☒ The allowed claim(s) is/are *1,3,4,12-14 and 16-18*.

☐ The drawings filed on _____ are accepted by the Examiner.

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

pplicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements oted below. Failure to timely comply will result in ABANDONMENT of this application.
HIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

achment(s)

☐ Notice of References Cited (PTO-892)
☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *03042004* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

MM

Examiner-Initiated Interview Summary	Application No. 10/009,009	Applicant(s) BRAIN ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1624	

All Participants:

(1) *Thomas McKenzie Ph.D.*.

(2) *Joseph Borovian*.

Status of Application: _____

(3) _____.

(4) _____.

Date of Interview: *3 March 2004*

Time: *9:00am*

Type of Interview:
- ☒ Telephonic
- ☐ Video Conference
- ☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☐ No
If Yes, provide a brief description:

Part I.

Rejection(s) discussed:
enablement for disease treatment

Claims discussed:
18

Prior art documents discussed:
none

Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:
Applicants agreed to limit claim 18 to the treatment of pain.

Part III.

☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

(Examiner/SPE Signature) (Applicant/Applicant's Representative Signature – if appropriate)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,009	12/20/2001	Christopher Thomas Brain	4-30972A	1971

1095 7590 03/04/2004

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
MCKENZIE, THOMAS C	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/04/2004

JJB

Please find below and/or attached an Office communication concerning this application or proceeding.

PLEASE TRANSMIT TO US IMMEDIATELY ART CITED ABROAD AND ADDITIONAL PERTINENT ART OF WHICH YOU ARE AWARE.

DOCKETED FOR: June 4 2004

Application No.	Applicant(s)	
10/009,009	BRAIN ET AL.	
Examiner	**Art Unit**	
Thomas McKenzie, Ph.D.	1624	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,12-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,4,12-14,16 and 17* is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *02/29/2004*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CASE 4-30972A/PCT

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 987587808 US — Express Mail Label Number

August 5, 2003 — Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF
BRAIN ET AL.
INTERNATIONAL APPLICATION NO: PCT/EP00/05059
FILED: 2 JUNE 2000
U.S. APPLICATION NO: 10/009,009
35 USC §371 DATE: 20 DECEMBER 2001
FOR: BRADYKININ RECEPTOR ANTAGONISTS

ART UNIT: 1624
EXAMINER: T. McKenzie

A 10

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

Responsive to the Official Action dated March 7, 2003, kindly amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on Page 3 of this paper.

Remarks/Arguments begin on Page 7 of this paper.

Case No. 4-30972 A/PCT

Application No. 10/009,009

Mailing Date: August 5, 2003

Due Date: August 7, 2003

Express Mail No.: EV 337527505 US

The Patent & Trademark Office acknowledges, and has stamped hereon the date of receipt of the items checked below:

- ☒ Amendment/Response/Letter - Fee $________
- ☐ Appln. Filing Papers - Fee $________
  - ☐ PCT National Stage
  - ☐ Provisional Application
  - ☐ RCE ☐ DIV ☐ CONT ☐ CIP
  - ☐ Specification ________ Pg's
- ☐ Executed/Unexecuted Decl. - Fee $________
  - ☐ Missing Parts/Missing Req.
- ☐ Preliminary Amendment ________ Pg's
- ☐ Claim of Priority ☐ Certified Copy(s)
- ☐ Amendment After Final
- ☐ Notice of Appeal - Fee $________
- ☐ Appeal Brief - Fee $________
- ☐ Issue Fee Payment $________
- ☐ Assignment Rec. Req. - Fee $________
- ☐ Formal Drawings ________ Pg's
- ☐ IDS________ Pg's - Fee $________
- ☐ PTO-1449 Form ________ Pg's
- ☒ Pet. for Ext. of Time - Fee $ 410.00
  84.00 (extra indep. claim)
  $494.00
- ☐ Application Data Sheet
- ☐ Seq. Listings ________ Pg's/Seq. Disk
- ☒ "new" abstract page
- ☒ extra copy of Page 9

JJB
Initials

82972/99A Rev.1

AMENDMENTS TO THE SPECIFICATION

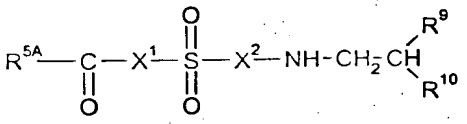
✓ Please replace the "original" Abstract with the "new" Abstract (attached hereto as a separate page) as Page 30 of the specification.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (original): A compound of formula IA



(IA)

wherein

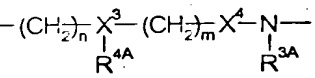
R^{5A} is $-X^{A}-R^{6A}$ or $-N(R^{7A})R^{8A}$, wherein

X^{A} is piperidinylene or piperazinylene,

R^{6A} is H, C_1-C_4alkyl, C_3- C_4alkenyl, C_3- C_4alkinyl, C_1-C_4(alkoxyalkyl), C_1-C_4(carboxyalkyl), a C_5-C_7heterocyclic group or phenyl- C_1-C_4alkyl;

R^{7A} is amino-C_2-C_4alkyl or mono- or di-(C_1-C_5alkyl)amino-C_2-C_5alkyl, and

R^{8A} is H, C_1-C_4alkyl or has the meanings as given for R^{7A};

X^1 is a divalent group of formula IA'  wherein

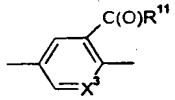
n is zero or 1;

X^3 is CH or N;

(a) X^4 is a direct bond, R^{3A} and R^{4A} together are ethylene and m is 2; or

(b) X^4 is a direct bond, R^{3A} is H, C_1-C_4alkyl,C_3-C_6cycloalkyl, C_3-C_6alkenyl, C_3-C_6alkinyl, C_7-C_{10}aralkyl, or C_6-C_9heteroaralkyl, R^{4A} is H and m is 1 or 2 or 3; or

(c) X^4 is $-CH(R^{12})-$, R^{3A} is H and R^{4A} and R^{12} together are propylene and m is 1, or ethylene and m is 2;

X^2 is a divalent group of formula IA"  wherein

X^3 is CH or N; and

R^{11} is C_1-C_4alkyl, C_3-C_6cycloalkyl or $-NR^{1A}R^{2A}$, wherein

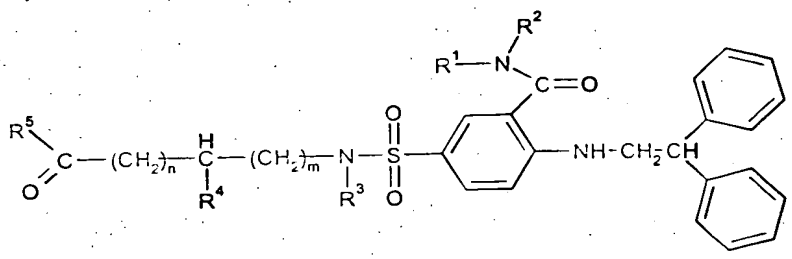
R^{1A} and R^{2A} independently are C_1-C_4alkyl or, together with the N-atom to which they are attached, represent a 5 to 7 membered heterocyclic ring; and

R^9 and R^{10} independently are a phenyl or pyridine ring;

and salts thereof.

Claim 2 (cancelled).

Claim 3 (original): A compound of formula I



(I)

wherein

R^1 and R^2 independently are C_1-C_4alkyl or, together with the N-atom to which they are attached, represent a 5 to 7 membered heterocyclic ring;

(a) R^3 and R^4 together are ethylene and m is 2; or

(b) R^3 is H, C_1-C_4alkyl, C_5-C_7cycloalkyl or phenyl-C_1-C_4alkyl, R^4 is H and m is 1 or 2 or 3;

n is zero ro 1; and

R^5 is -X-R^6or -N(R^7)R^8, wherein

X is  ,

R^6 is C_1-C_4alkyl, C_3-C_4alkenyl, C_3-C_4alkinyl, C_1-C_4(alkoxyalkyl), C_1-C_4(carboxyalkyl), a C_5-C_7heterocyclic group or phenyl-C_1-C_4alkyl;

$R^7$is amino-C_2-C_4alkyl or mono- or di-(C_1-C_5alkyl)amino-C_2-C_5alkyl, and

$R^8$is H, C_1-C_4alkyl or has the meanings as given for R^7;

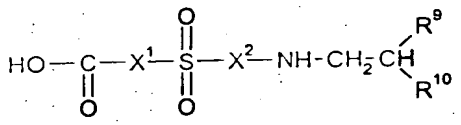
and salts thereof.

Claim 4 (original): A compound according to claim 1 which is {2-(2,2-diphenyl-ethylamino)-5-[4-(4-isopropyl-piperazine-1-carbonyl)-piperidine-1-sulfonyl]-phenyl}-morpholin-4-yl-methanone, or {2-(2,2-diphenyl-ethylamino)-5-[4-(4-methyl-piperazine-1-carbonyl)-piperidine-1-sulfonyl]-phenyl}-morpholin-4-yl-methanone.

Claims 5-11 (cancelled).

Claim 12 (new). The compound 2-(2,2-diphenylethylamino)-5-(4-aminocarbonyl-piperidine-1-sulfonyl)-benzoic acid amide or a 2-(2,2-diphenylethylamino)-5-(aminocarbonyl-C_2-C_4alkylene-aminosulfonyl)-benzoic acid amide compound, or a salt of said compounds.

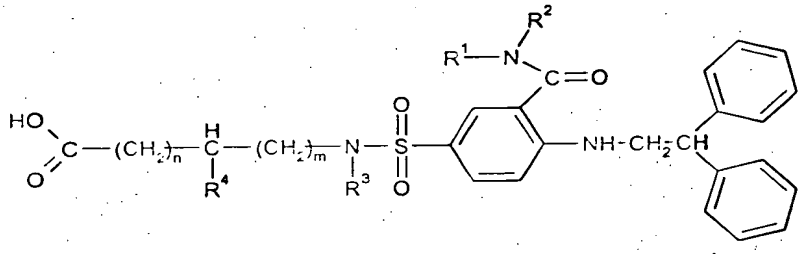
Claim 13 (new). A process for preparing a compound of formula IA according to claim 1 which comprises: 1) in a first step, reacting a compound of formula IIA.



(IIA)

where X^1, X^2, R^9 and R^{10} are as defined in claim 1, with thionyl chloride and a catalytic amount of dimethylformamide to obtain the corresponding acid chloride compound; and 2) in a second step, coupling the acid chloride compound obtained in the first step by adding it to an amine to obtain the desired compound of formula IA in free base or, if desired, salt form.

Claim 14 (new). A process for preparing a compound of formula I according to claim 3 which comprises: 1) in a first step, reacting a compound of formula II



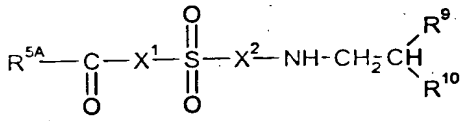
(II)

where R^1, R^2, R^3, R^4, m and n are as defined in claim 3, with thionyl chloride and a catalytic amount of dimethylformamide to obtain the corresponding acid chloride compound; and 2) in a second step, coupling the acid chloride compound obtained in the first step by adding it to an amine to obtain the desired compound of formula I in free base or, if desired, salt form.

Claim 15 (new). A method of treating a disease which is responsive to the antagonism of bradykinin activity comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound according to claim 1, or a pharmaceutically acceptable salt thereof.

Claim 16 (new). A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a compound according to claim 1, or a pharmaceutically acceptable salt thereof.

Claim 17 (new). A compound having the formula



wherein

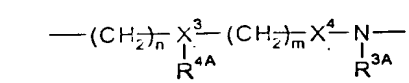
R^{5A} is $-X^A-R^{6A}$ or $-N(R^{7A})R^{8A}$, wherein

X^A is piperidinylene or piperazinylene,

R^{6A} is H, C_1-C_4alkyl, C_3-C_4alkenyl, C_3-C_4alkinyl, C_1-C_4(alkoxyalkyl), C_1-C_4(carboxyalkyl), a C_5-C_7heterocyclic group or phenyl- C_1-C_4alkyl;

R^{7A} is amino-C_2-C_4alkyl or mono- or di-(C_1-C_5alkyl)amino-C_2-C_5alkyl, and

R^{8A} is H, C_1-C_4alkyl or has the meanings as given for R^{7A};

X^1 is a divalent group of formula IA'  wherein

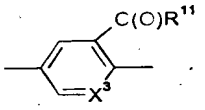
n is zero or 1;

X^3 is CH or N;

(a) X^4 is a direct bond, R^{3A} and R^{4A} together are ethylene and m is 2; or

(b) X^4 is a direct bond, R^{3A} is H, C_1-C_4alkyl, which may be unsubstituted or substituted by halogen, C_3-C_6cycloalkyl or aryl, C_3-C_6cycloalkyl, C_3-C_6alkenyl, C_3-C_6alkinyl, C_7-C_{10}aralkyl, which may be unsubstituted or substituted by halogen, methoxy, nitro or C_1-C_4alkyl which may be unsubstituted or substituted by halogen, or C_6-C_9heteroaralkyl, which may be unsubstituted or substituted by C_1-C_4alkyl, R^{4A} is H and m is 1 or 2 or 3; or

(c) X^4 is -CH(R^{12})-, R^{3A} is H and R^{4A} and R^{12} together are propylene and m is 1, or ethylene and m is 2;

X^2 is a divalent group of formula IA"  wherein

X^3 is CH or N; and

R^{11} is C_1-C_4alkyl, C_3-C_6cycloalkyl or -$NR^{1A}R^{2A}$, wherein

R^{1A} and R^{2A} independently are C_1-C_4alkyl or, together with the N-atom to which they are attached, represent a 5 to 7 membered heterocyclic ring; and

R^9 and R^{10} independently are a phenyl or pyridine ring, both of which may be unsubstituted or substituted by one or more halogen atoms;

and salts thereof.

REMARKS/ARGUMENTS

A favorable reconsideration of this application is respectfully requested in view of the foregoing amendments and the following remarks.

Applicants acknowledge the Examiner's detailed critique of the instant specification and the "original" claims and gratefully appreciate the suggestions proposed by the Examiner for expediting prosecution, of which many, if not all, have been adopted in this Amendment.

By the foregoing amendment to the specification, the "original" Abstract has been replaced by a "new" Abstract.

Claims 1-11 were presented for examination, and Claims 1, 3, 4 and 12-17 are now present in the case.

Claim 2 has been cancelled and replaced by "new" Claim 12.

Claims 5 and 6 have been cancelled and replaced by "new" Claims 13 and 14, respectively.

Claims 7-9 have been cancelled without replacement.

Claims 10 and 11 have been cancelled and replaced by "new" Claims 15 and 16, respectively.

"New" Claim 17 has been added, support for which may be found in Claim 1 coupled with the disclosure on Page 2, lines 3-11.

The Examiner's objection to the "original" Abstract is believed to have been overcome by the submission of a "new" Abstract which is believed to be more acceptable.

The Examiner's objection to Claim 8 under 37 CFR 1.75 as being a duplicate of Claim 1 is believed to have been mooted by the cancellation of said claim.

The Examiner has rejected Claim 2 under the second paragraph of 35 USC 112 as being "indefinite". This rejection is believed to have been overcome by the cancellation of Claim 2 and its replacement with "new" Claim 12.

Claims 5 and 6 (inadvertently referred to by the Examiner as Claims 5-7) have been rejected under the second paragraph of 35 USC 112 as being incomplete for omitting essential steps. This rejection is believed to have been overcome by the cancellation of Claims 5 and 6 and their replacement with "new" Claims 13 and 14, respectively.

The Examiner's rejection of Claim 7 under the second paragraph of 35 USC 112 as being "indefinite" is believed to have been mooted by the cancellation of said claims.

The Examiner's rejection of Claims 8 and 9 under 35 USC 101 as being "non-statutatory" is believed to have been mooted by the cancellation of said claims.

The Examiner has rejected Claims 10 and 11 under the second paragraph of 35 USC 112 as being "indefinite". This rejection is believed to have been overcome by the cancellation of Claims 10 and 11 and their replacement with "new" Claims 15 and 16. More particularly, the passage "a disease or condition in which bradykinin B_1 receptor activation plays a role or is implicated" objected to by the Examiner has been replaced by a more acceptable passage in "new" Claim 15 , whereas all language relating to its intended use has been excluded from "new" Claim 16.

Lastly, the Examiner has rejected Claims 9-11 under the first paragraph of 35 USC 112 for lack of enablement. Although the Examiner acknowledges that the instant specification is enabling for preventing pain, he contends that it is not enabling for preventing any other diseases. In this connection, the tenor of the Examiner's comments regarding this rejection appears to revolve around the terms "prevention" and "preventing" which appear in said claims.

First of all, Claim 9 has been cancelled. Secondly, Claim 10 has been replaced by "new" Claim 15, which claim is believed to contain a more acceptable passage and does not contain the term "prevention" and "preventing". Thirdly, Claim 11 has been replaced by "new" Claim 16, which claim is devoid of any "use" language. However, to the extent that this rejection has not been overcome by the cancellation of Claim 9 and the replacement of Claims 10 and 11 with "new" Claims 15 and 16, respectively, then this rejection is traversed.

Since the instant specification discloses a test method which is utilized for determining the usefulness of a compound as a bradykinin B_1 receptor antagonist (see, in this connection, Page 19, line 1 to Page 20, last line), coupled with the test results set forth on Page 20, last four lines, it is clear that all of the compounds of the instant claims exhibit bradykinin B_1 receptor antagonist activity and, therefore, share the same pharmacological reactivity. Accordingly, there can be no question that one skilled in the art would conclude that all of the compounds embraced by the instant claims would be useful in treating all diseases responsive to the antagonism of bradykinin activity, i.e., those disclosed in the instant specification, those disclosed in the literature and heretofore undisclosed indications which respond to the antagonism of bradykinin activity.

In view of the foregoing, it is clear that there is simply no basis for "lodging" a "non-enabling" rejection under the first paragraph of 35 USC 112 against "new" Claims 15 and 16.

Applicants additionally acknowledge the Examiner's indication that Claims 1, 3 and 4 are allowed. However, in view of the foregoing amendments and remarks, it is Applicants' belief that "new" Claims 12-17 are allowable.

All of the objections and rejections of record having been overcome, the instant application is deemed to be in condition for allowance, and an early notice to that effect is earnestly solicited.

Six "new" claims were added by this Amendment, including two independent claims. Although the total number of claims now present in the case does not exceed the highest number previously paid for, the total number of independent claims exceeds the highest number previously paid for by one. Moreover, since this Amendment will be deemed to have been filed more than four months from, but within five months of, the date of the Office Action (i.e., March 7, 2003), it is respectfully requested that the period for filing a response to said Office Action be extended by two months. Please charge the $84.00 required by 37 CFR 1.16(b) for an extra independent claim and the $410.00 required by 37 CFR 1.17(a)(2) for a two-month extension of time, i.e., a total fee of $494.00, to Deposit Account No. 19-0134 in the name of Novartis Corporation. In this connection, an additional copy of this page is appended.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080

Joseph J. Borgvian
Agent for Applicants
Reg. No. 26,631
(862) 778-7801

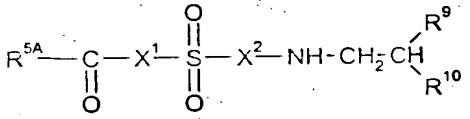
JJB/pk

Encls.: "new" Abstract page
extra copy of this page
postcard

Date: August 5, 2003

Abstract

The invention relates to sulfonyl amine derivatives of formula IA



(IA)

wherein R^{5A}, X^1, X^2, R^9 and R^{10} are as defined herein, which derivatives are useful as bradykinin B_1 receptor antagonists.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,009	12/20/2001	Christopher Thomas Brain	4-30972A	1971

1095 7590 03/07/2003

THOMAS HOXIE
NOVARTIS, PATENT AND TRADEMARK DEPARTMENT
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER
MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/07/2003

CAL JJB

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PLEASE TRANSMIT TO US IMMEDIATELY ART CITED ABROAD AND ADDITIONAL PERTINENT ART OF WHICH YOU ARE AWARE.

DOCKETED FOR: June 7, 2003

Office Action Summary	Application No.	Applicant(s)	
	10/009,009	BRAIN ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3 and 4* is/are allowed.

6)☒ Claim(s) *2 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

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